



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 26, 2015

MAKO Surgical Corporation
% Terry Sheridan Powell
M Squad Associates, Incorporated
575 Eighth, Avenue, Suite 1212
New York City, New York 10018

Re: K142606

Trade/Device Name: Trident[®] Tritanium[®] PST[®] Acetabular Shells

Regulation Number: 21 CFR 888.3358

Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated
uncemented prosthesis

Regulatory Class: Class II

Product Code: LPH, JDI

Dated: December 22, 2014

Received: December 29, 2014

Dear Terry Sheridan Powell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Lori A. Wiggins -S

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K142606

Device Name

Trident® Tritanium® PST® Acetabular Shells

Indications for Use (Describe)

The Trident® Tritanium® PST® Acetabular Shell System is indicated for use in skeletally mature individuals undergoing surgery for total hip replacement due to:

- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis, or congenital hip dysplasia;
- Acute traumatic fracture of the femoral head or neck;
- Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty or total hip replacement.

The Trident® Tritanium® PST® Acetabular Shell is intended for cementless or cemented fixation. The porous structured surface provides biological fixation when used in a cementless application.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

Traditional 510(k): Trident® Tritanium® PST® Acetabular Shells
MAKO Surgical Corp.

This 510(k) Summary is provided in accordance with the requirements of 21 CFR 807.92.

1.1. Device Name and Classification

Device Trade Name:	Trident® Tritanium® PST® Acetabular Shells
Device Common Name:	Artificial Total Hip Replacement
Regulation Number and Description:	888.3358 - Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis; and 888.3350 - Hip joint metal/polymer semi-constrained cemented prosthesis
Device Class:	II
Product Codes:	LPH - prosthesis, hip, semi-constrained, metal/polymer, porous uncemented JDI - prosthesis, hip, semi-constrained, metal/polymer, cemented
Advisory Panel:	Orthopedic

1.2. Address and Registration

Submitter's Name:	MAKO Surgical Corp.
Address:	3 Wing Drive Suite 102 Cedar Knolls, NJ 07927
Establishment Registration Number:	3009701876
Contact Person:	Jonathan Reeves
Telephone Number:	954-628-0665
Fax Number:	954-927-0446
Date Summary Prepared:	January 8, 2015

1.3. Purpose of Submission

The Trident® Tritanium® PST® Acetabular Shell is a new device.

1.4. Identification of Legally Marketed Device to which Submitter Claims Equivalence

The subject device is substantially equivalent to the following predicate devices:

Device Description	510(k) Numbers
PST® Acetabular Shells (and dome hole plug)	K112802
Trident® Tritanium®, Trident® PSL® and Trident® Hemispherical Shells	K081171, K983382, K013676

1.5. Device Description

The subject Trident® Tritanium® PST® Acetabular Shell is the predicate PST® Acetabular Shell, which has been modified to incorporate the acetabular bearing mating features of the predicate Trident® Tritanium®, Trident® PSL®, and Trident® Hemispherical Shells, to allow compatibility with existing Stryker Orthopaedics acetabular bearings including the Trident polyethylene and Modular Dual Mobility (MDM) bearing families.

The subject Trident® Tritanium® PST® Acetabular Shells are manufactured from titanium alloy and feature a porous structured surface. The subject shells feature a dome hole, and are available either in a solid shell (no screw holes) configuration, or in a cluster screw hole configuration for optional supplemental bone screw fixation. The subject Trident® Tritanium® PST® Acetabular Shells are compatible with the optional predicate PST Acetabular Shell system bone screws (titanium alloy), with the optional predicate Stryker Orthopaedics Torx head acetabular dome hole occluder (CP titanium), and with an optional new hex head acetabular dome hole occluder (titanium alloy).

1.6. Intended Use

The Trident® Tritanium® PST® Acetabular Shell System is indicated for use in skeletally mature individuals undergoing surgery for total hip replacement due to:

- A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, avascular necrosis, or congenital hip dysplasia;
- Acute traumatic fracture of the femoral head or neck;
- Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty or total hip replacement.

The Trident® Tritanium® PST® Acetabular Shell is intended for cementless or cemented fixation. The porous structured surface provides biological fixation when used in a cementless application.

1.7. Comparison of Technological Characteristics

The subject Trident® Tritanium® PST® Acetabular Shells have the same indications for use, same outer profile, same porous structured surface, and are made from the same materials using the same manufacturing, similar packaging, and same sterilization methods as the predicate PST® Acetabular Shells. The subject Trident® Tritanium® PST® Acetabular Shells incorporate the acetabular bearing mating features of the predicate Trident® Tritanium®, Trident® PSL® and Trident® Hemispherical Shells, and are therefore compatible with existing Stryker acetabular bearings, including the Trident polyethylene and Modular Dual Mobility (MDM) bearing families.

1.8. Performance Testing

Comparisons of materials, manufacturing methods, and design features, as well as disassembly testing per ASTM F1820 (including push-out, lever-out, and torsional testing) for the subject shells with the worst case style and size of compatible Stryker Orthopaedics acetabular bearings, were relied upon to demonstrate the substantial equivalence of the modified subject device to the predicate devices.

1.9. Clinical Testing

Clinical testing was not required to demonstrate substantial equivalence to the predicates.

1.10. Conclusions

The subject Trident® Tritanium® PST® Acetabular Shells share the same indications for use, same outer profile, same porous structured surface, and are made from the same materials using the same manufacturing, similar packaging, and same sterilization methods as the predicate PST® Acetabular Shells. The subject Trident® Tritanium® PST® Acetabular Shells share the acetabular bearing mating features of the predicate Trident® Tritanium®, Trident® PSL® and Trident® Hemispherical Shells, for compatibility with the same predicate Trident polyethylene and Modular Dual Mobility (MDM) bearing families. Therefore, the subject Trident® Tritanium® PST® Acetabular Shells are substantially equivalent to the identified predicate acetabular shells.